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EXAMINER
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ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,416	KORBER, ALFRED	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,10,11 and 13-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,10,11 and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1, 6 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eis et al. WO 95/07683, in view of Serpelloni US 7,201,922.

Eis teaches a composition comprising from about 75% to about 99.999% of carrier material including coolants such as menthyl lactate (abstract; page 4, 1st paragraph; and page 7, 2nd paragraph). The composition can be compressed into tablet (page 10, 2nd paragraph).

Eis does not expressly teach the claimed compression force. However, Serpelloni teaches compressed tablet prepared by applying compression force of at least 13.4 kN (table 5). Thus, it would have been obvious to one of ordinary skill in the art to prepare the tablet of Eis using compressed force in view of the teaching of Serpelloni to obtain the claimed invention. This is because Serpelloni teaches using the claimed compressed force to prepare a compressed dosage form is well known in pharmaceutical art, because Serpelloni teaches using a compressed force within the claimed range to obtain tablet having pharmaceutically acceptable hardness, and because Eis teaches tablet dosage forms using a compressed method.

It is noted that Eis does not explicitly teach the claimed storage stability. However, the burden is shifted to applicant to show that the compressed tablet of Eis does not exhibit the claimed storage stability. This is because Eis teaches the use of the claimed coolant in the claimed amount in a compressed dosage form. Accordingly, the use of the same ingredients would necessitate the claimed properties. Products of

identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 1, 6 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kajs et al. US 5,397,573, in view of Eis et al. WO 95/07683 and Serpelloni US 7,201,922.

Kajs teaches a laxative composition comprising from about 1% to about 99% menthol (abstract; and column 3, lines 7-65). The composition is formulated into solid dosage forms including tablet (column 4, lines 19-25).

Kajs does not explicitly teach the claimed coolant such as menthyl lactate. However, Eis teaches coolants include menthol or menthyl lactate (page 3, last paragraph through page 4, 1st paragraph). Thus, it would have been obvious to one of ordinary skill in the art to modify the laxative composition of Kajs using menthyl lactate as a coolant in view of the teaching of Eis, because Eis teaches menthyl lactate is a well known coolant in pharmaceutical art, and because Kajs teaches the use of peppermint oil, menthol or pharmaceutically acceptable esters of menthol such as menthol acetate.

It is noted that the references do not expressly teach the claimed compression force. However, Serpelloni teaches compressed tablet prepared by applying compression force of at least 13.4 kN (table 5). Thus, it would have been obvious to one of ordinary skill in the art to prepare the tablet of Kajs in view of Eis using

compressed force taught by Serpelloni to obtain the claimed invention. This is because Serpelloni teaches using the claimed compressed force to prepare a compressed dosage form is well known in pharmaceutical art, because Serpelloni teaches using a compressed force within the claimed range to obtain tablet having pharmaceutically acceptable hardness, and because Kajs teaches tablet dosage prepared by any known method in pharmaceutical art.

It is noted that Kajs does not explicitly teach the claimed storage stability. However, the burden is shifted to applicant to show that the compressed tablet of Kajs in view of Eis does not exhibit the claimed storage stability. This is because Eis teaches the use of the claimed coolant in a compressed dosage form. Accordingly, the use of the same ingredients would necessitate the claimed properties. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 4, 5, 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eis et al. WO 95/07683, in view of Serpelloni US 7,201,922 and Kuhn et al. US 5,783,725.

Eis is relied upon for the reasons stated above. Eis does not expressly teach the claimed menthyl lactate such as L-lactic acid L-menthyl ester having purity of at least 95%.

Kuhn teaches a stable lactic acid menthyl ester comprising L-lactic acid L-menthyl ester having purity of 99.7% (abstract; and column 2, lines 42-44). Thus, it would have been obvious to one of ordinary skill in the art to prepare the dosage form of Eis using the menthyl lactate in view of the teaching of Kuhn to obtain the claimed invention. This is because Kuhn teaches a menthyl lactate that is shelf stable for several months with no changes in smell, because Kuhn teaches the use of menthyl lactate as a cooling agent in pharmaceutical preparations (column 1, lines 5-53), and because Eis teaches the use of menthyl lactate as a cooling agent in a pharmaceutical composition to obtain a formulation useful in pharmaceutical art.

Claims 4, 5, 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kajs et al. US 5,397,573, in view of Eis et al. WO 95/07683 and Serpelloni US 7,201,922 and Kuhn et al. US 5,783,725.

Kajs is relied upon for the reasons stated above. Kajs does not expressly teach the claimed menthyl lactate such as L-lactic acid L-menthyl ester having purity of at least 95%.

Kuhn teaches a stable lactic acid menthyl ester comprising L-lactic acid L-menthyl ester having purity of 99.7% (abstract; and column 2, lines 42-44). Thus, it would have been obvious to one of ordinary skill in the art to prepare the dosage form of Kajs using menthyl lactate as a cooling agent in view of the teaching of Kuhn to obtain the claimed invention. This is because Kuhn teaches menthyl lactate having cooling action desired for pharmaceutical preparations, Kuhn teaches a menthyl lactate that is

shelf stable for several months with no changes in smell (column 1, lines 5-53), and because Kajs teaches the desirability of using a cooling agent in formulations useful in pharmaceutical art.

Response to Arguments

Applicant's arguments filed 10/23/07 have been fully considered but they are not persuasive.

The obviousness type double patenting rejection is withdrawn in view of applicant's remarks filed 10/23/07 at pages 5-6.

Applicant argues that the cited patents provide no suggestion of forming a compact of a menthyl ester. As noted in the Action, Eis et al. discloses a composition comprising at least 75 wt% of a carrier. As disclosed on page 7 of Eis et al., the composition comprises 75 to 99.999% by weight of a carrier. Eis et al. does not disclose or suggest the carrier being menthol as suggested in the Action. Furthermore, Eis et al. clearly does not disclose a composition comprising 75 to 99 wt% menthol as suggested in the Action. Thus, the statement on page 5 of the Action indicating that Eis et al. discloses the claimed coolant in the claimed amount is clearly incorrect.

However, in response to applicant's argument, applicant's attention is called to page 7, lines 8-10 and 14, Eis clearly teaches the composition comprises from about 75% to about 99.999% carrier materials including coolant. At page 3, lines 32 through page 4, lines 1-2, Eis teaches coolants include menthyl lactate.

Applicant argues that Eis et al. provides no suggestion of using menthol or menthyl lactate in its natural form. The passages referred to in the Action refer to menthol and menthyl as a reactant to produce one or more phosphate derivatives. As specifically disclosed on page 3, lines 15-24, the phosphate compounds are formulated by phosphorylating a coolant, sweetener, or flavorant component. Thus, the menthol referred to in Eis et al. is a reactant that is phosphorylated to form the desired phosphate derivative. Accordingly, Eis et al. provides no suggestion of forming a compact from menthol or menthyl lactate as asserted in the Action. Moreover, page 6, lines 11-13 specifically disclose the phosphate derivatives being present in an amount of 0.001 to 25 wt% of the total composition. Thus, the amount of the menthol phosphate derivative is well below the claimed range.

However, in response to applicant's argument regarding the amount of coolant, it is clear from Eis that carrier includes coolant, and that the carrier is being used in an amount from about 75%-99.999%. Applicant's attention is called to page 2, lines 6-20, Eis teaches the amount for the phosphate derivatives of from about 0.001% to about 25% is in addition to the amount of carrier being from 75% to 99.999%. Further, in response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., menthol or menthyl lactate in its natural form) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Serpelloni is relevant only to the extent that a tablet or pellet is formed. The resulting tablet of Serpelloni includes granules of lactose and starch. This has no relation to the claimed invention or the composition of Eis et al. Accordingly, the combination of Eis et al. and Serpelloni provide no suggestion of forming a mechanically compressed lactic acid menthyl ester where the compact comprises at least 95 wt% lactic acid menthyl ester. Accordingly, claim 1 is not obvious over Eis et al. and Serpelloni. Claims 6 and 13-16 are also not obvious for reciting additional features of the invention that are not disclosed or suggested in the combination of the cited patents.

In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Serpelloni is relied upon solely for the teaching of compression force suitable to obtain tablet having pharmaceutically acceptable hardness.

Applicant argues that Kajs et al., Eis et al. and Serpelloni either standing alone or in combination provide no suggestion of forming a mechanically compressed compact containing at least 95 wt% lactic acid menthyl ester as recited in claim 1. As noted in the Action, Kajs et al. is directed to a laxative composition comprising menthol. Kajs et al. does not disclose that menthyl lactate is an equivalent for use in the laxative

composition. Furthermore, the Action provides no basis for the position that it would have been obvious to replace the menthol of Kajs et al. with the menthyl lactate for a laxative composition. Moreover, Kajs et al. does not suggest a compact comprising at least 95 wt% of menthol or lactic acid menthyl ester. Kajs et al. discloses menthol which is typically in the form of peppermint oil. Thus, the actual menthol content of Kajs et al. in the final composition is not disclosed.

However, in response to applicant's argument, it is noted that Kajs teaches a solid dosage form such as tablet comprising 1-99% of menthol or ester of menthol, and 1-99% peppermint oil (column 3, lines 61-68). Peppermint oil is well known in the art as a coolant (column 3, lines 23-27). Eis teaches coolant includes menthyl lactate. Thus, it would have been obvious to one of ordinary skill in the art to modify the peppermint oil of Kajs using menthyl lactate as a coolant in view of the teaching of Eis, because Eis teaches menthyl lactate is a well known coolant in pharmaceutical art, and because Kajs teaches the use of peppermint oil, menthol or pharmaceutically acceptable esters of menthol such as menthol acetate.

Applicant argues that Kuhn et al. is cited for disclosing lactic acid menthyl ester in a stabilized form by the addition of an alkali metal carbonate and/or bicarbonate and/or alkaline earth metal carbonate and/or bicarbonate. Kuhn et al. provides no suggestion of a mechanically compressed lactic acid menthyl ester to form a compact comprising at least 95 wt% lactic acid menthyl ester. The method and composition of Kuhn et al. form a solution of the lactic acid menthyl ester in acetone with sodium bicarbonate. The

solution is allowed to cool to form crystals of the lactic acid menthyl ester. There is no suggestion of a mechanically compressed lactic acid menthyl ester as claimed. Moreover, Kuhn et al. also discloses that lactic acid menthyl ester is generally unstable and produces a pungent smell which renders it unusable for most intended uses. See, for example, column 1, lines 37-40. Kuhn et al. is specifically directed to crystallizing the lactic acid menthyl ester in the presence of a carbonate or bicarbonate salt to form shelf stable crystals. Kuhn et al. provides no indication that lactic acid menthyl ester can be mechanically compressed to form a stable composition as in the claimed invention.

However, in response to applicant's argument, it is noted that the transitional phrase "comprising of" in the preamble of the claims do not preclude the present of an alkali metal carbonate. Moreover, it is noted that claim 14 is not rejection over Kuhn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
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